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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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George Gullickson

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EXAMINER

PAPAPIETRO, JACQUELINE M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,486	<b>Applicant(s)</b> GULLICKSON ET AL.	
	<b>Examiner</b> JACQUELINE PAPAPIETRO	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 14-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo (US 6530897 B2) in view of Lowe et al (US 6709667 B1).

Regarding claims 1-4, 9 and 14-21, Nardeo discloses a steerable catheter comprising: an elongated catheter body (100, Fig 7) including a proximal end, a distal segment (Fig 1 ) and a deflection lumen extending from the proximal end toward the distal segment (15, Figs 1 and 2); a handle (200, Fig 7) coupled to the catheter body proximal end and including a longitudinal axis; and a deflection mechanism (220) for selectively inducing a bend in the catheter body; the deflection mechanism comprising: an elongated deflection wire (50) extending within the deflection lumen of the catheter body and into the handle; a thumb wheel (steering dial 220) mounted within the handle; wherein rotation of the thumb wheel in a first direction moves the deflection wire proximally through the deflection lumen inducing a first bend of the catheter body, and a rotation of the thumb wheel in a second direction moves the deflection wire, inducing a second bend of the catheter body (column 4 lines 63-66); wherein the handle further includes a first major side (213, Fig 6) and a second major side (214) and the thumb wheel is disposed intermediate the first major side and the second major side (see Fig 6); wherein the handle further includes a first handle body portion and a second handle body portion joined along a plane substantially perpendicular to the thumb wheel axis;

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the first handle body portion and the second handle body portion capturing the thumb wheel there between (see figs 6-8); wherein the deflection mechanism further comprises a securing mechanism (locking device 230, Fig 7) selectively engageable in use from either the first major side or the second major side of the handle to apply a friction force, which holds the thumb wheel preventing further rotation of the thumb wheel (column 5 lines 23-29); wherein the handle further includes a first minor side (215, Fig 7) extending between the first major side and the second major side and a first thumb wheel window (218) extending through the first minor side through which a portion of the thumb wheel is exposed (see Figs 6-8); wherein the handle further includes a second minor side opposite the first minor side (216, Fig 7), and a second thumb wheel window (see Figs 7 and 8) extending through the second minor side through which a second portion of the thumb wheel is exposed, wherein the thumb wheel includes a side wall forming an outer rim, the outer rim being exposed through the first thumb wheel window (see Figs 7-8) and the second thumb wheel window, wherein the outer rim includes serrations (222, Fig 7) and first and second indentations (any of the indentations formed by teeth 222, see Fig 7).

Nardeo discloses a deflection mechanism wherein rotation of the wheel is translated into a forward-and-back motion of the deflection wire. Nardeo also discloses that the wire may terminate on a gear or other device mechanically controlled by the motion of the thumb wheel (column 4 line 67- column 5 line 2). Nardeo does not specifically disclose a guide track, rack arm, runners, pinion gear, or linear rack.

Lowe teaches a catheter with a deployment system comprising a rack and pinion. The deployment system comprises a guide track (shown in Figures 1B, 11F, and 11G) formed within the handle in substantial alignment with the longitudinal axis; a thumb wheel (33) mounted proximal to the guide track within the handle and supporting a pinion gear (35), the thumb wheel and pinion gear adapted to be rotated about a common thumb wheel axis (column 8 lines 52-57), which extends substantially perpendicular to the longitudinal axis (Fig 11G); and a rack arm (37) including runners received by the guide track, an attachment point coupling a sheath to the rack arm (see Fig 11G) and a linear rack (37) engaging the pinion gear (Fig 1B); the rack arm extending within the handle, obliquely to the longitudinal axis (when the longitudinal axis has been defined as the axis formed along the line from the center of the thumb wheel to the distal opening in the handle, see Fig 1B), from the runners to the linear rack, the attachment point being moveable along a linear path that is substantially aligned with the lumen (Fig 11D and 11F); wherein rotation of the thumb wheel in a first direction moves the linear rack proximally, via the engagement of the linear rack with the pinion gear (column 8 lines 52-57), to draw the sheath proximally through the lumen and along the guide track (see Figs 11D and 11F); wherein rotation of the thumb wheel in a second direction moves the linear rack distally, via the engagement of the linear rack with the pinion gear, to push the sheath along the guide track and through the lumen (Fig 1B, inherent to the disclosed mechanism).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Nardeo by including the rack and pinion

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mechanism as taught by Lowe, as an alternative to the deflection mechanism of Nardeo, in order to move the deflection wire proximally and distally, thereby creating a bend in the catheter body. Nardeo discloses that gears or other devices may be used to drive the deflection mechanism. Because the mechanisms of Nardeo and Lowe are used to create a proximal and distal movement of a wire/sheath it would have been obvious to substitute one mechanism for the other.

Regarding claims 5-8 and 27, Nardeo discloses the catheter as described above, wherein the thumb wheel includes an internal axial extension (see Figs 7 and 8), a sidewall forming an outer rim (220, Figs 7 and 8) and a circumferentially extending slot / arcuate opening through the outer rim of the sidewall (Figs 7 and 8). The thumb wheel includes a first sidewall and a second sidewall joined along a longitudinal place substantially perpendicular to the thumb wheel axis, the junction of the first side wall and the second sidewall forming a circumferentially extending slot (Figs 7 and 8). Lowe discloses the catheter as described above, wherein the pinion gear (35, Fig 1B) is formed on the thumb wheel (33) and the rack arm (37) extends next to the thumb wheel so as to engage with the pinion (Figs 1B, 11D, and 21), and wherein the handle includes an inwardly extending guide that holds the linear rack of the rack arm against the pinion gear of the thumb wheel (Fig 1B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Nardeo in view of Lowe as described above, and configuring the device with the thumb wheel includes the internal axial extension, sidewall, and slot of Nardeo such that the pinion gear is formed on the internal axial extension and the rack arm extends through the

circumferentially extending slot to engage the pinion gear with an inwardly extending guide passing through the slot / opening to hold the rack against the pinion gear in order to contain all the elements within the thumb wheel so that it is less likely that the rack and pinion become misaligned.

Regarding claims 22 and 23, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to form the guide track such that it includes track sides engaging the runners of the rack arm and to form the rack arm with an H-shaped cross-section defining the runners because Applicant has not disclosed that this specific configuration and shape provides and advantage, is used for a particular purpose, or solves a stated problem. Furthermore, it is common to form a rack arm with an H-shaped cross-section that defines runners which engage track sides of a guide track. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Nardeo in view of Lowe to obtain the invention was specified in claims 22 and 23.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo in view of Lowe as applied to claim 9 above, and further in view of Thompson et al (US 5358478).

Nardeo in view of Lowe discloses the catheter of claim 9, as described above, but does not disclose a resilient compressible member. Thompson teaches a steerable catheter (10) with a thumb wheel (18 and 34, Fig 1), deflection wire (58), and deflection mechanism (Fig 2) comprising a securing mechanism (locking lever 38, Fig 1)

selectively engageable to apply friction, which holds the thumb wheel and prevents rotation of the thumb wheel (column 4 lines 10-24). The securing mechanism comprises a resilient compressible member (an O-ring) disposed in the gap between the thumb wheel sidewall and one of the first major side and the second major side of the handle body (column 4 lines 13-14). Thompson also teaches the catheter wherein one of the first major side and the second major side of the handle includes a window and a thumb slide extending therethrough (locking lever 38, Fig 1); the thumb slide adapted to apply a lateral force pushing the thumb wheel against the resilient compressible member thereby engaging the securing mechanism (column 4 lines 10-24); wherein the securing mechanism further includes an elongated ring (the screw 24 and threaded washer 26) coupled to the thumb slide whereby the thumb slide applies the lateral force by wedging the elongated ring between the thumb wheel and one of the first major side and the second major side (via the screw mechanism); further comprising means to adjust the gap between the thumb wheel sidewall and the one of the first major side and the second major side of the handle body (by increasing the seating force on the cam, see column 4 lines 10-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the locking mechanism of Thompson in the catheter of Nardeo in view of Lowe in order to prevent rotation of the wheel when no further bending of the catheter is desired.

Furthermore, where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of



the art. In re Kuhle, 526 F.2d 553,555, 188 USPW 7, 9 (CCPA 1975). Applicant has not disclosed that the securing mechanism of the instant application is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the securing mechanism of Nardeo or Thompson, or the securing mechanism of the instant application because both mechanisms successfully stop the thumb wheel from further rotation. Therefore, it would have been an obvious matter of design choice to modify Nardeo to obtain the invention as specified in claims 10-13.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo in view of Lowe as applied to claim 1 above, and further in view of Biggs (US 6030360).

Nardeo in view of Lowe discloses the catheter of claim 1, with the features described above, wherein the handle is ergonomically designed (column 4 lines 51-52), but does not specifically disclose a narrowed waist. Biggs teaches a steerable catheter wherein a handle includes a first major (312U, Fig 1B) side and a second major side (312L); the first and second major sides forming a thumb wheel support segment and a grasping segment extending proximally from the support segment (see Figs 1A-2B); the grasping segment including a narrowed waist (see Fig 2A) facilitating ergonomic handling. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the narrowed waist of Biggs in the steerable

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catheter of Nardeo in view of Pearson in order to make it easier and more comfortable for the user to hold the instrument.

### ***Response to Arguments***

Applicant's arguments filed on January 24, 2008 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE PAPAPIETRO whose telephone number is (571)272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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